Europäisches Patentamt
European Patent Office
Office européen des brevets

European Patent Office
80298 MUNICH
GERMANY
Tel. +49 (0)89 2399 - 0
Fax +49 (0)89 2399 - 4465

Vossius & Partner
P.O. Box 86 07 67
81634 München
ALLEMAGNE

EINGEGANGEN
Vossius & Partner
26. Juli 2010
Frist bearb.: fah

Formalities Officer
Name: Pepper Cano
Tel.: 5636
or call:
+31 (0)70 340 45 00

Date: 23-07-2010

Reference	Application No./Patent No.
S1305 EP	04713966.2 - 2403 / 1618177

Applicant/Proprietor: Protalix Ltd.

Summons to attend oral proceedings pursuant to Rule 115(1) EPC

You are hereby summoned to attend oral proceedings arranged in connection with the above-mentioned European patent application.

The matters to be discussed are set out in the communication accompanying this summons (EPO Form 2906).

The oral proceedings, which will not be public, will take place before the Examining Division.

on 04.10.10 at 09.30 hrs at the EPO,
PschorrHöfe, Bayerstr. 34, D-80335 München

No changes to the date of the oral proceedings can be made, except on serious grounds (see OJ EPO 1/2009, 68). If you do not appear as summoned, the oral proceedings may continue without you (R. 115(2) EPC, see also OJ EPO 10/2008, 471).

Your attention is drawn to Rule 4 EPC, regarding the language of the oral proceedings, and to the Special edition No. 3 OJ EPO 2007, L.1., concerning the filing of authorisations for company employees and lawyers acting as representatives before the EPO.

The final date for making written submissions and/or amendments (R. 116 EPC) is 03.09.10.

The actual room number as well as the waiting room numbers will be given to you by the porter in the foyer at the above EPO address.

Parking is available free of charge in the underground car park. However, this applies only in the case of accessing the car park via the entrance "Zollstrasse".

1st Examiner:
Chakravarty A

2nd Examiner:
Turri M

Chairman:
Marinoni J

For the Examining Division

Annexes:
Confirmation of receipt (Form 2936)
Communication (EPO Form 2906)

Europäisches Patentamt • European Patent Office • Office européen des brevets

Registered letter with advice of delivery

to EPO postal service: 21.07.10

The examination is being carried out on the **following application documents**

Description, Pages

1, 4-13, 15-18, 20-29, 33, 55-62, 64, 66	filed with telefax on	22-06-2009

Claims, Numbers

1-47	filed with telefax on	22-06-2009

Drawings, Sheets

1/17-17/17	as published

1 This communication accompanies a summons to oral proceedings, as requested by the applicant should the examining division consider refusing the application.

Novelty - Art. 54 EPC /Clarity - Art. 84 EPC

2 Art. 84: The nature of the molecule claimed in claim 16 is unclear. The current wording of the claim reads on any molecule produced by a plant cell. Even if the claim were reformulated to be directed to human lysosomal glucocerebrosidase produced by a plant cell, the structure of the resulting protein would not be clear. Neither the sequence nor the glycosylation pattern would be clearly determined by such a claim, it is not clear if the claimed protein still includes the C- and N-terminal signals and the exact nature of the glycosylation will vary depending on the particular embodiment, e.g. the host plant.

C

3 Moreover, according to the Guidelines, C-III, 4.11, where the invention relates to a product, it may be defined as a product of a process only if no clearer definition is possible. This is not the case here since the product could be defined structurally.

4 Art. 54 EPC: The examining division is also of the opinion that even a claim reformulated to be directed to human lysosomal glucocerebrosidase produced by a plant cell lacks novelty over D1-D3 and D6.

5 The examining division is of the opinion that to objections of lack of novelty raised in our communication of 31.10.07 apply, mutatis mutandis to the present claims. The applicant has argued that the prior art does not anticipate the claimed subject-matter because in the protein disclosed in D6 has a glycosylation patterns which differs form that of the claimed molecule, due to glycosylation patterns differing substantially between plant and animal cells. The recombinant glycoprotein disclosed in D6 cannot have the exposed mannose and xylose and/or fucose residues of the claimed human lysosomal proteins.

6 However, the applicant has not provided any evidence to support his allegation that the protein of D6 does not have at least 1 exposed mannose and a at least 1 xylose residue. This is assuming that the requirements of claim 39 are the same as those of claim 16 .

7 With regard to D1, the applicant's arguments centre around the lack of a precise characterisation of the protein disclosed therein. The examining division points out that the lack of a precise characterisation in the prior art does not amount to proof of a difference between the claimed subject-matter and the prior art. Once a *prima facie* case of lack of novelty has been made, the burden of proof to show at difference between the prior art and the claimed subject-matter lies with the applicant.

This applies equally to the disclosure of D2 and D3.

8 The examining division also maintains the objection of under Art. 56 EPC raised in the communication of 31.10.07.

Unity of Invention- Art. 82 EPC

9 In response to an objection under Art. 82 EPC, the applicant has elected to restrict the claims to Group 5 of the inventions identified in the supplementary European search report.

10 In the applicant's letter dated 17.03.08 the following arguments are presented on page 7:

The (then pending claims) 1-65 are united by the single general inventive concept of human lysosomal proteins having plant-specific glycosylation (xylose and/or fucose residues), and at least one exposed mannose residue, which has not been disclosed in any of the cited documents.

11 However, the present claims still lack unity of invention because they relate to subject-matter not linked by a common single general inventive concept as required by Art. 82 EPC and Rule 44 EPC.

12 In particular, the examining division now identifies two groups of inventions in the present claims:

1- Claims 1-15, 31-37: plants cells expressing a human lysosomal glucocerebrosidase

2- Claims 16-30, 38-47: human lysosomal glucocerebrosidase produced by the plants of Group 1

Although both groups involve human lysosomal glucocerebrosidase, this cannot be seen as a single common general inventive concept in the sense of Rule 44 EPC because the enzyme is known per se (see the section on novelty above).

Additional formal objections

13 Claims 1 and 31 (plant cells) and 16, 39 and 43 (proteins) have been drafted as separate independent claims.

Under Article 84 in combination with Rule 43(2) EPC, an application may contain more than one independent claim in a particular category only if the subject-matter claimed falls within one or more of the exceptional situations set out in paragraph (a), (b) or (c) of Rule 43(2) EPC. This is not the case in the present application.

In the further prosecution of the application, failure to file an amended set of claims which complies with Rule 43(2) EPC, or to submit convincing arguments as to why the current set of claims does in fact comply with these provisions, may lead to refusal of the application under Article 97(2) EPC.

14 In claims 31 and 32 it is not clear what is meant by the term a preparation is.

15 **Correction according to Rule 139 EPC**

The applicant has requested that SEQ ID NO: 8 be corrected to include an additional sequence.

The requirements for correction according to Rule 139 are:

That, if the request for such correction concerns the claims, the correction must be obvious in the sense that it is immediately evident that nothing else would have been intended than what is offered as the correction.

Thus, it must be immediately apparent that an error has occurred and also immediately obvious what the correction must be. It goes without saying that a correction may not add subject-matter beyond the content of the application as originally filed.

None of the above conditions are fulfilled for the presently requested correction.

It is not immediately obvious that a error has occurred. The skilled reader seeing the original SEQ ID NO: 8 would not come to the conclusion that it must represent an error. That human lysosomal glucocerebrosidase can have a number of different sequences is apparent from the present application itself. Claim 1 has been formulated without the mention of any specific sequence, presumably because a number of different sequences are possible. In the claims, a particular sequence is only mentioned in a dependent claim.

Moreover, it is not immediately obvious what the correction should be. The chosen correction is one a any number of possibilities.

Thus, the examining division cannot allow the requested correction.